RENEW: A BLINDED RANDOMIZED CLINICAL INVESTIGATION OF REFLUXSTOP COMPARED WITH NISSEN FUNDOPLICATION IN THE TREATMENT OF GASTROESOPHAGEAL REFLUX DISEASE

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BACKGROUND

- Traditional anti-reflux surgeries like Nissen fundoplication have significant complications such as dysphagia, inability to belch, and gas-bloating; leading to patient dissatisfaction, operative failures, and reoperations[1]
- RefluxStop repairs the defunct anti-reflux barrier by[2,3]:
  - Restoring the physiological anatomy of the gastroesophageal junction (GEJ)
  - Repositioning and maintaining the closing sphincter between the stomach and esophagus away from the opening in the diaphragm
  - Avoiding encirclement of the food passageway, thereby subverting side effects observed with existing standard of care (**Figure 1**)

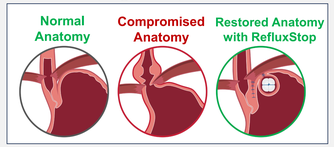


Figure 1: Reconstruction of ARB with RefluxStop

- Previous studies demonstrated that RefluxStop[2,3]:
  - Significantly improves GERD health-related quality of life (GERD-HRQL) scores (>90%)
  - Reduces proton pump inhibitor (PPI) use (>95%)
  - Achieves near-complete resolution of GERD symptoms
  - Maintains very low rates of adverse events (AEs) and negligible adverse device effects (ADEs) such as explantations, esophageal dilations, dislocations, or migrations
- A prospective, single-arm, multicenter clinical investigation of RefluxStop confirmed its long-term effectiveness and safety in treating GERD over 4 years, supporting continued evaluation versus standard of care in ongoing studies, including RENEW—a RCT comparing RefluxStop with Nissen fundoplication[3]

STUDY DESIGN

Objective and Trial Design

- RENEW is a prospective, blinded, multicenter, double-arm RCT
- Objective: Assess safety and *Patient Reported Outcomes - Side Effects (PROS)* of RefluxStop compared with Nissen fundoplication (**Figures 2** and **3**)
- Patients with the following key eligibility criteria are being randomized 1:1 to undergo either surgery with RefluxStop or Nissen fundoplication (**Figure 2**):
  - ≥18 years of age
  - Documented GERD for ≥12 months confirmed by abnormal 24-hour pH monitoring
  - Off PPI therapy for ≥7 days

Primary Endpoint (6 months)

- The primary endpoint of the study is **Patient-Reported Outcome - Side Effects (PROS)**—a composite measure of dysphagia, odynophagia, inability to belch/vomit, and gas-bloating (**Figure 3**)

Secondary Endpoints

Secondary endpoints of the study include (**Figures 3** and **4**):

- **PROS** (re-assessed at 1-year)
- **Reduction in GERD (RIG)**: Effectiveness of reflux control (i.e., composite of 24-hour pH monitoring and GERD-HRQL scores; assessed at 6 and 12 months)
- **Operative failures score (OFS)**: Combining no of reoperations, esophageal dilatations, reherniations, and resumption of daily PPI use; 6 months)
- **Incidence of AEs** Including procedure-related and serious AEs, ADEs, device deficiencies (DDs); 3, 6, and 12 months)

Other assessments

- Other assessments include surgical injury and leakage, hiatal stenosis, device position, endoscopic evaluations (Bravo capsule placement, esophagitis, gastritis, Barrett's esophagus), procedure time, hospital stay, and treatment-related costs
- Patient questionnaires assessing quality of life and symptom control including GERD-HRQL, brief esophageal dysphagia questionnaire (BEDQ), regurgitations (episodes/week), inability to belch/vomit, daily PPI use, patient dissatisfaction, gas-bloating (scale 0 to 5), EuroQol-5D 5-level (EQ-5D-5L), work productivity and activity impairment (WPAI), and healthcare resource utilization (HCRU)

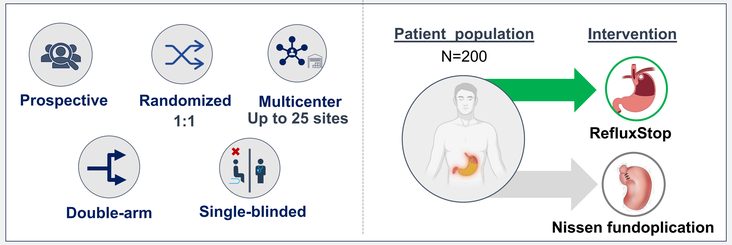


Figure 2: RENEW Study Design

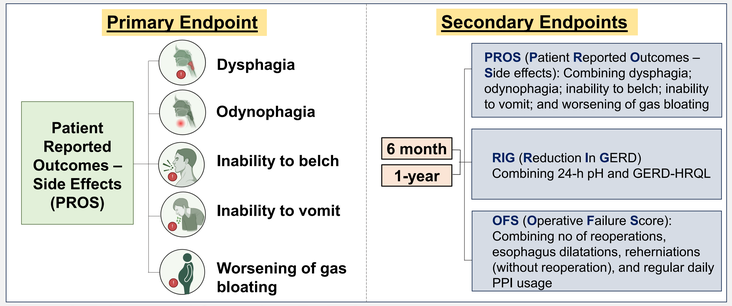


Figure 3: Primary and Secondary Endpoints

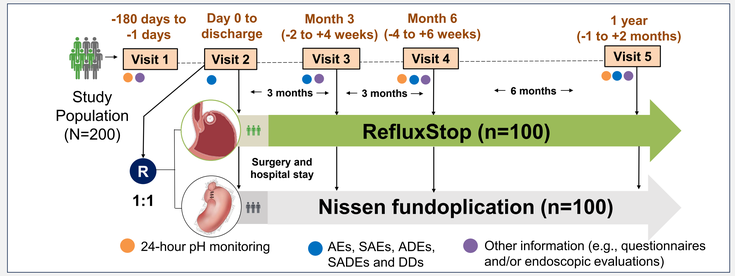


Figure 4: Visit Schedule and Assessments

RESULTS

- **Enrollment**: Q2 2025
- **Expected completion**: Q2 2026
- **Final data**: Expected Q4 2026

CONCLUSIONS

The completed RCT is expected to provide critical data on the effectiveness and safety of RefluxStop compared to Nissen fundoplication

REFERENCES

1. Zehetner J, et al. Looking back on a gold standard: a systematic literature review of laparoscopic Nissen fundoplication as an anti-reflux treatment option. *Eur Surg*. 2024;56(2):143-171.
2. Bjelović M, et al. Non-active implantable device treating acid reflux with a new dynamic treatment approach: 1-year results : RefluxStop™ device; a new method in acid reflux surgery obtaining CE mark. *BMC Surg*. 2020;20(1):159.
3. Harsányi L, et al. Treating acid reflux without compressing the food passageway: 4-year safety and clinical outcomes with the RefluxStop device in a prospective multicenter study. *Surg Endosc*. 2024;38(10):6060-6069.

DISCLOSURES

Prof. Schoppmann declares receiving travel grants from Implantica AG for conference attendance

RefluxStop is not approved in USA
RefluxStop is not for sale in USA